

Remarks

After amendment, claims 1-35 are pending in the present application, the claims having been amended primarily to address the Examiner's §112, second paragraph rejection and to eliminate any reading of the claims onto the compound of example VI of the Linder reference (page 164), cited against the originally filed claims. Claims 1, 12, 13 and 21 have been amended, and claims 33-35 are newly added. Claims 21-32 were allowed. Claim 1 has been amended to delete any reference to a compound wherein m is 1 and R is H. Claim 12 has been amended primarily to change the use of the open-ended term "comprising" to the term "consistent essentially of". Claim 12 is now directed to pharmaceutical compositions which are used specifically to treat or alleviate the symptomology of menopause using an effective amount of the claimed compound. The breadth of claim 12 is now directed to a pharmaceutical composition which is used to treat or alleviate the symptomology of menopause using the amended claimed compound (R can also be H) and includes any additional component which does not change the basic and novel characteristics of the compositions which are used to treat menopause symptoms. Claim 21 has been amended to point out that pharmaceutically acceptable salts of the claimed compound where R is H are also claimed. New claims 33-35 are added to avoid the insertion of negative limitations into independent claim 1. Support for the amendment to the claims can be found throughout the originally filed specification and claims. No new matter has been added by the present amendment.

The Examiner has rejected originally filed claims 1-32 variously under 35 U.S.C. §112, second paragraph, §102 and §103, for the reasons which are stated of record. Applicant shall address each of the Examiner objections/rejections in the sections which follow.

The §112, Second Paragraph Rejection of the Claims

The Examiner has rejected claim 11 as including a term which renders the claim indefinite. Applicant has amended claim 11 and made reference to substituent R, rather than to claim 10.

It is respectfully submitted that the claims, after amendment fully comply with the requirements of 35 U.S.C. §112, second paragraph.

The §102 Rejection

The Examiner has rejected original claims 1 and 12 as being anticipated by Linder, et al., *Steroids*, Vol. 29(2), pp. 161-170 (1977) ("Linder"). It is the Examiner's view that original claims 1 and 12 read on the teachings of Linder, and in particular, Example VI on page 164. Applicant respectfully submits that the instant claims are no longer even arguably anticipated by the teachings of Linder.

Linder is directed to the use of a number of steroid compounds which are conjugated or bonded to bovine serum albumin and administered to laboratory animals to elicit an immunogenic response in the animal so as to isolate immunizers (e.g. antibodies) which may be used in radioimmune assays. Claim 1 of the present application has been amended to eliminate any possible reading of claim 1 onto example VI of Linder. Consequently, claim 1 is no longer anticipated by Linder.

Turning to claim 12, this claim is now directed specifically to pharmaceutical compositions which are administered to patients with menopause and *consist essentially of* the claimed steroid compound in an amount which is effective to treat the symptomology of menopause in the patients. The pharmaceutical compositions do not claim the use of any steroid/bovine serum albumin conjugate and such use to treat the symptoms of menopause would actually *be contrary* to pharmaceutical practice. It is completely inconsistent with, indeed contrary to, the present invention that the instantly claimed pharmaceutical compositions would function to elicit an undesirable immunogenic response in a patient. Such a response would be contraindicated and would require cessation of therapy. Inasmuch as Linder actually teaches away from the present pharmaceutical compositions, claim 12 is now patentable. Note that no other biological activity of the disclosed steroid compounds is discussed in Linder.

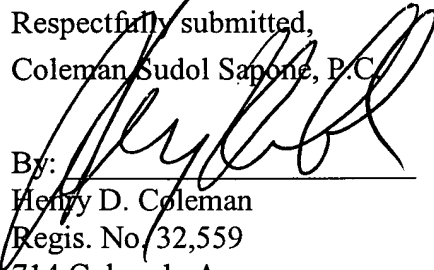
The §103 Rejection

The Examiner has rejected claims 19 and 20 as being obvious over the teachings of Linder. Applicant respectfully traverses the Examiner's rejection and respectfully submits that claims 19 and 20 are patentable. In particular, as discussed above, Linder does not teach the composition of claim 12 as presently claimed. Indeed, for the reasons cited above, Linder actually teaches away from the present invention which is set forth in claim 12 because Linder

teaches compositions which produce an immunogenic response in a laboratory animal to isolate immunizers such as antibodies to be used in assays. There is no disclosure or even a hint of suggestion that the compounds which are disclosed in Linder may be desirably used as in pharmaceutical compositions for the treatment of menopause symptoms in a patient. Indeed, as explained above, the disclosure of Linder actually teaches away from the present pharmaceutical compositions. Inasmuch as it is submitted that claim 12 is non-obvious over Linder, it is axiomatic that claims 19 and 20 which are directed to specific dosage forms of the patentable pharmaceutical composition of claim 12 are also non-obvious over Linder and clearly patentable.

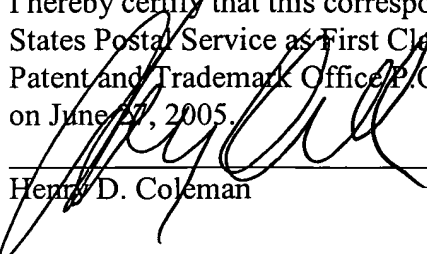
For the above reasons, Applicant respectfully asserts that the claims set forth in the amendment to the application of the present invention are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and such action is earnestly solicited. Applicants previously have neither cancelled nor added any claim to the present application.

A fee in the amount of \$150.00 is due and enclosed for the presentation of one additional independent claim and two additional dependent claims (small entity status applies). If any additional fee is due or any overpayment has been made, please charge/credit Deposit Account No. 04-0838.

Respectfully submitted,
Coleman Sudol Sapon, P.C.

By: _____
Henry D. Coleman
Regis. No. 32,559
714 Colorado Avenue
Bridgeport, Connecticut 06605-1601
(203) 366-3560

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Henry D. Coleman